

CLAIMS

1. Polymorphic Form C of base ondansetron,
5 characterised in that its powder X-ray diffraction pattern
presents characteristic peaks at 14.97 and 20.86° 2θ and
presents no peaks beneath 6.5° 2θ.

2. Polymorphic Form D of base ondansetron,
10 characterised in that its powder X-ray diffraction pattern
presents characteristic peaks at 11.29°; 14.58°; 17.16°;
18.89°; 20.28°; 21.22°; 25.06° and 27.49° 2θ.

3. Polymorphic Form E of base ondansetron,
15 characterised in that its powder X-ray diffraction pattern
presents characteristic peaks at 6.29°; 11.09°; 11.88°;
12.69°; 14.97° and a doublet at (24.96°; 25.17°) 2θ.

4. Polymorphic form according to Claim 1,
20 characterised in that its powder X-ray diffraction pattern
also presents a peak at 25.50° 2θ.

5. Polymorphic form according to Claim 4,
characterised in that its powder X-ray diffraction pattern
25 presents the following peaks:

2θ (°)
7.18
10.96
13.13
14.97
16.08
16.42
19.73
20.86

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21.82
24.08
24.70
25.50
26.73
27.59
28.97

6. Polymorphic form according to Claim 5, characterised in that it presents a powder X-ray diffraction pattern in accordance with Figure 1.

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7. Polymorphic form according to Claim 2, characterised in that its powder X-ray diffraction pattern presents the following peaks:

2θ (°)
5.58
7.10
7.26
10.77
10.92
11.29
13.23
13.65
14.58
14.74
15.23
15.38
15.92
16.22
16.48
17.16
17.86
18.89
20.28
20.71
21.22
21.98
22.84

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23.53
24.12
24.75
25.06
26.03
26.17
26.56
26.79
27.49
27.91
28.75
29.41

8. Polymorphic form according to Claim 7, characterised in that presents a powder X-ray diffraction pattern in accordance with Figure 2.

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9. Polymorphic form according to Claim 3, characterised in that its powder X-ray diffraction pattern presents the following peaks:

2θ (°)
6.29
7.06
10.50
11.09
11.88
12.69
13.10
13.57
14.97
16.33
16.93
17.40
18.58
19.28
20.71
21.08
21.28
22.10
24.12
24.71

24.96
25.17
25.73
26.65
26.93
28.18
28.53
29.34
29.76

10. Polymorphic form according to Claim 9, characterised in that it presents a powder X-ray diffraction pattern in accordance with Figure 3.

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11. Process for preparing the polymorphic form according to Claim 1, characterised in that it comprises:

- a) preparation of a saturated solution of base ondansetron at room temperature in dichloromethane;
- 10 b) precipitation of the crystalline form by addition of a C₅-C₇ alkane; and
- c) recovery of the crystalline form.

12. Process according to Claim 11, characterised 15 in that said C₅-C₇ alkane is n-hexane or n-pentane.

13. Process for preparing the polymorphic form according to Claim 2, characterised in that comprises:

- a) dissolution of base ondansetron in a C₁-C₄ alcohol 20 at reflux;
- b) addition of t-butyl-methyl-ether followed by cooling; and
- c) recovery of the crystalline form.

25 14. Process for preparing the polymorphic form according to Claim 3, characterised in that it comprises:

- a) dissolution of the ondansetron hydrochloride in a mixture of a C₁-C₃ alcohol and water;

- b) precipitation of the base ondansetron by basification of the solution;
- c) filtering the solid and washing with water;
- d) suspension of the water-moistened solid obtained in 5 stage c) with methanol at reflux with stirring; and
- e) recovery of the crystalline form.

15. Process according to any of claims 13 or 14, characterised in that said alcohol is methanol.

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16. Process according to Claim 14, characterised in that the basification of stage b) is carried out by addition of an aqueous ammonia solution.

15 17. Pharmaceutical composition that includes a polymorphic form according to any of claims 1 to 10, in a therapeutically active amount and with a suitable amount of at least one excipient.

20 18. Polymorphic form according to any of claims 1 to 10 for use for manufacturing a drug for the treatment and prophylaxis of post-operative nausea and vomiting and for the control of nausea and vomiting induced by radiotherapy and cytotoxic chemotherapy.

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